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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/644,588	08/20/2003	Connie Sanchez	05432/100M919-US3	5265
7278	7590	03/27/2007		
DARBY & DARBY P.C. P. O. BOX 5257 NEW YORK, NY 10150-5257			EXAMINER BETTON, TIMOTHY E	
			ART UNIT	PAPER NUMBER
			1614	
SHORTENED STATUTORY PERIOD OF RESPONSE		MAIL DATE	DELIVERY MODE	
3 MONTHS		03/27/2007	PAPER	

**Please find below and/or attached an Office communication concerning this application or proceeding.**

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

# Office Action Summary

Application No.

10/644,588

Applicant(s)

SANCHEZ ET AL.

Examiner

Timothy E. Betton

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 20 November 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 21, 23, 25, 27, 29, 31, 33, 35 and 37 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 21, 23, 25, 27, 29, 31, 33, 35, and 37 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

## Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date 1 sheet.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_.

**DETAILED ACTION**

com. AM  
3-17-07

Applicant's ~~election~~ traverse in the reply filed on 20 November 2006 is acknowledged. The traversal is on the ground(s) that instant claims 23, 29, and 35 disclose definite subject matter to overcome 35 USC 112, second paragraph rejection.

Applicants' further traverse on the grounds that instant claims 21,23,25,27,29,31,33,35,and 37 are not overcome by obviousness In the 35 USC 103(a) rejection. However, applicants' allegations are not drawn to factual support in relevance to overcoming said rejections cited above. Therefore, applicants' arguments are not found persuasive.

Applicants' arguments, filed 20 November 2006, have been fully considered but they are not deemed to be persuasive. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant invention.

The requirement is still deemed proper and is therefore made FINAL.

***Status of the Claims***

Claims 21,23,25,27,29,31,33,35, and 37 are pending for prosecution on the merits. Instant claims 23 have been amended to correct a grammatical error.

***Claim Rejections - 35 USC § 112, 2<sup>nd</sup> Paragraph***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

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The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

Claims 23, 29, and 35 remain rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. It is noted that claim 23 has been amended to recite "to obtain a significant improvement" as measured by the CGI improvement and severity subscale." However, this limitation still renders the claims indefinite because the term is not defined by the claim or the specification what change or how much of a change is considered to be "a significant improvement" in the patient.

***Claim Rejections - 35 USC § 103(a)***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be

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negated by the manner in which the invention was made.

Claims 21, 23, 25, 27, 29, 31, 33, 35, and 37 are rejected under 35 U.S.C. 103 (a) as being unpatentable over Patris M, et al. ("Citalopram versus fluoxetine; a double-blind, controlled, multicentre, phase III trial in patients with unipolar major depression treated in general practice," 1996 International Clin Psychopharm 11: 129-136), in view of Boegesoe et al. (US Pat. 4,943,590), and further in view of Bilski et al. (US Pat. 4,764,361).

Patris et al. teach the administration of citalopram in the treatment of patients with major depression (abstract). Patients had a score of 30 on the MADRS at the beginning of the 8-week treatment period (see Fig. 1 p. 132). The reference teaches assessment of the efficacy of treatment by measuring the MADRS score as well as by the CGI severity and improvement scale (see pp. 130 and 134).

Patris et al. do not teach escitalopram (the S-enantiomer) specifically. Boegesoe et al. teach that antidepressant drug citalopram has two enantiomers, (+)-citalopram (which is escitalopram) and (-)-citalopram, and that the entire 5-HT uptake inhibition activity resides in the (+) enantiomer (i.e. escitalopram) (see: abstract; col. 1, lines 1-28; col. 2, lines 9+). The reference also teaches separation of the two enantiomers to yield pure citalopram enantiomers (see col. 2, lines 51 - col. 7, line 25). The reference teaches, "a method for alleviating depression in a living animal body subject thereto" by administering an effective amount of the compound or pharmaceutically acceptable salts (which is

escitalopram), at dosages ranging from 0.10-100 mg and preferably 5-50 mg daily (overlapping the dosage of current claim 25). (See: abstract; col. 8 Table 1; col. 8, lines 55-66; claims 1-2 & 7-12).

While Boegesoe et al. teach pharmaceutically acceptable salts; the reference does not teach oxalate salts specifically.

Bilski et al. teaches the oxalate and crystalline oxalate salts of the (S) is form of a racemic mixture. The reference does not teach escitalopram.

It would have been obvious to one of ordinary skill in the art to use the oxalate or crystalline oxalates salt of escitalopram in the instantly claimed method of treating severe depression, having been taught by the prior art that it is known to make oxalate and crystalline oxalate salts of a racemic compound to obtain the (S) isoform and motivated by the desire to obtain the (S)/(+) isoform salt of citalopram (i.e. escitalopram), which is known to be the racemate wherein the pharmaceutical antidepressant activity resides.

Claims 21, 23, 25, 27, 29, 31, 33, 35, and 37 are rejected. No claims are allowed.

### **Conclusion**

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Timothy E. Betton whose telephone number is (571) 272-9922. The examiner can normally be reached on Monday-Friday 8:30a - 5:00p.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin H. Marschel can be reached on (571) 272-0718. The fax phone

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number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

*Ardin H. Marschel* 3/17/07  
**ARDIN H. MARSCHEL**  
**SUPERVISORY PATENT EXAMINER**

TEB